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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/687,532	10/15/2003	Bernard Andreas	021629-002100US	5238

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EXAMINER	
HOUSTON, ELIZABETH	

ART UNIT	PAPER NUMBER
3731	

DATE MAILED: 06/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/687,532	ANDREAS ET AL.	
	Examiner	Art Unit	
	Elizabeth Houston	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 October 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-45* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3 and 9-45* is/are rejected.

7)☒ Claim(s) *4-8* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *15 October 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *022805*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Double Patenting

1. Claims 1, 4, 7, 12-18, 19, 22-44, 43, 65, 66 provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1-5, 7, 14, 16, 18, 19, 36, 42-47, 50-52, 57 of copending Application No. 10/306,813 in view of Konya (USPN 6,123,723).

2. Claims 1, 4, 7, 12, 16-18, 22-28, 32-37 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1-5, 7, 14, 16, 18, 19, 36, 42-47, 50-52, 57 of copending Application No. 10/412,714 in view of Konya.

3. Claims 1-3, 12, 16-18, 22-28, 32-40 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1, 4, 6, 7, 16-18, 20 of copending Application No. 10/944,282 in view of Konya.

4. Claims 1-3,12, 16-18, 22-28, 32-37, 41-44 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1, 4, 5, 7-12, 18, 22-25, 28-33, 39, 40, 42-45, 55, 57-60, 63, 64 of copending Application No. 10/794,405 in view of Konya.

5. The copending applications disclose all of the limitations of the instant claims except for the implantable carrier. Konya discloses a multiplicity of stents and a graft, which is well known in the art for treating aortic aneurysm. The graft is analogous with the implantable carrier. It would have been obvious to one having ordinary skill in the art

at the time of the invention to incorporate a stent-graft into the invention of the copending application.

This is a provisional obviousness-type double patenting rejection.

Claim Objections

6. Claims 27 and 36 recites the limitation "one of the stent segments" in line 2. Claims 1 and 32 recite "plurality of stent segments". There is insufficient antecedent basis for this limitation in the claim. It is also unclear whether "each membrane" is coupled with "one of the stent segments" is a many to one relationship (more than one membrane coupled to one stent) or a one to one relationship (one membrane for one stent).

7. Claim 22, 23, 28 and 37 are objected to because of the following informalities: "Stent segments" should be "Plurality of stent segments" for clarity and to stay consistent with the claim language of claim 1. Appropriate correction is required.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 1-3, 9-12, 16-18, 22-28, 32-37 and 41-44 rejected under 35 U.S.C. 103(a) as being unpatentable over Chermoni (USPub 2002/0156496) in view of DiCaprio (USPN 6,123,712) in view of Konya (USPN 6,123,723).

10. Chermoni discloses a stent delivery device comprising a catheter shaft with an expandable balloon (104), and a plurality of stent segments, and a carrier shaft (605) coupled to the stents and disposed over the catheter shaft. Part of the carrier shaft is disposed proximal to the stents.

11. Chermoni does not disclose a sheath.

12. DiCaprio discloses a stent delivery device that uses a guide catheter/sheath (11). The guide catheter would be slidably disposed over the stents (and implantable carrier disclosed below) and would constrain expansion of the proximal portion of the expandable member and the stents (and implantable carrier) when placed partially over the expandable member.

13. It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate the use of a guide catheter because it is well known in the art to use a guide catheter to protect the vessel from trauma caused by the stents during delivery. The inventions are analogous with each other and the instant invention and therefore the combination is proper.

14. Chermoni in view of DiCaprio does not disclose the implantable membrane.

15. Konya discloses a multi-stent graft wherein the graft covering represents the implantable membrane and the individual rings of the stents represent the stent segments. The graft membrane comprises multiple dividable or frangible connections in

that it is capable of being ripped, or torn, or cut and therefore divided, and additionally since it semi-porous. The graft membrane is made of a polymer that is semi-porous (permeable) or nonporous (impermeable) (Col 11, line 39-44). The membrane is solid wall (non-porous) or a tubular mesh (semi-porous) or a tubular scaffold (add rigidity to the stent (Col 12, line 38)). The stent segments (each ring of the stent) are fixedly disposed along the membrane carrier (Figs 6-8). The membrane is a continuous membrane coupled with a plurality of stent segments (each ring of the stent). Konya discloses more than one stent graft combination and so there is a plurality of membranes, each membrane is with two or more of the stent segments.

16. It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate a graft membrane onto a stent to add rigidity to the stent prevent the stent segments from separating or getting entangled. Konya offers the motivation (Col12, lines 35-40) for the combination.

17. Chermoni in view of DiCaprio in view of Konya discloses the invention substantially as claimed as stated above. However Chermoni in view of DiCaprio in view of Konya fails to disclose that the implantable carrier comprises a coil or axial beams. The instant disclosure describes this parameter as merely preferable and does not describe it as contributing any unexpected result to the stents delivery device. As such this parameter is deemed a matter of design choice (lacking in any criticality) and well within the skill of the ordinary artisan, obtained through routine experimentation in determining optimum results.

18. Claims 13, 29 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chermoni (USPub 2002/0156496) in view of DiCaprio (USPN 6,123,712) in view of Konya (USPN 6,123,723) as applied to claims 1 and 32 above, and further in view of Letendre (USPN 6,267,783).

19. Chermoni in view of DiCaprio in view of Konya disclose all the limitations of the claimed invention as stated above except that the membrane is biodegradable.

20. Letendre discloses using biodegradable material so that the graft can erode and dissolve over a period of time (Col 6, line 30-33).

21. It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate the use of a biodegradable material to avoid having foreign objects in the body for an infinite amount of time. It is well known in the art to use biodegradable material as evidenced by Letendre. The inventions are analogous with each other and the instant invention and therefore the combination is proper.

22. Claims 14, 15, 30, 31, 39 and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chermoni (USPub 2002/0156496) in view of DiCaprio (USPN 6,123,712) in view of Konya (USPN 6,123,723) as applied to claims 1 and 32 above, and further in view of Barry (US Pub 2002/0037358).

23. Chermoni in view of DiCaprio in view of Konya disclose all the limitations of the claimed invention as stated above except that membrane is coupled with a drug.

24. Barry discloses a graft that can be coated with a polymeric material/drug agent matrix (Para 0029). The drug agents used include anti-inflammatory and anti-proliferative agents (Para 0036).

25. It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate a drug into the graft since it is well known in the art to use coat stent-grafts with drugs to simultaneously treat the wounded vessel while providing structure to open the vessel. Further it is well known to incorporate drugs to prevent thrombosis and restenosis. The inventions are analogous with each other and the instant invention and therefore the combination is proper.

Allowable Subject Matter

26. Claims 4-8 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

27. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

a. Delivery devices that deliver multiple stents: Polaskyj Stockert (USPN 5,662,675); Bleam (USPN 6,143,016); Kugler (USPN 6,129,756); Hartley (US 2003/0225446); Shaknovich (USPN 5,807,398); McDonald (USPN 6,090,136).

b. Multiple stents with implantable membrane: Parodi (USPN 5,709,701), Gianturco (USPN 5,282,824); Horzewski (USPN 6,325,823).

c. Multiple Stents: Camrud (USPN 6,258,117); Jayaraman (USPN 5,755,781); Wolf (USPN 5,104,404

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Houston whose telephone number is 571-272-7134. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

eh

ANHTUAN T. NGUYEN
SUPERVISORY PATENT EXAMINER
6/12/06